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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,905	12/14/2001	Paul M. Ridker	B0801/7238 (ERG/KA)	7653

7590 11/06/2007

Edward R. Gates
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210

EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
11/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/017,905	RIDKER ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,11,16,21,52,55,57,62-68 and 71-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,11,16,21,52,55,57,62-68 and 71-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 8/08/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 8/08/07, have been entered.

2. Claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68, and 71-76 are being acted upon.

3. In view of the amendments all previous rejections have been withdrawn.

4. The following are new grounds for rejection.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68, and 71-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez-Moran et al. (1999) in view of Rohlfing, C.L., et al. (2000) and Chapin. B.L., et al. (1999).

Rodriguez-Moran et al. teaches that elevated serum CRP levels have been found in type II diabetics and in diabetics with foot ulcers (see particularly page 211, column 2). The reference also teaches that elevated serum CRP levels are also found in noncontrolled type II diabetic patients. (see particularly Table 2).

Rodriguez-Moran et al. does not teach the characterizing a risk profile for developing diabetes in an apparently healthy individual nor evaluating the likelihood that an individual will benefit from treatment.

Rohlfing et al. teaches the use of a screening assay for undiagnosed diabetes and/or complications thereof (see particularly page 187 and CONCLUSIONS).

Chapin et al. teaches that even apparently healthy individuals who undergo regular physical examinations can suffer from undiagnosed diabetes and/or complications thereof (see particularly Table 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made measure serum CRP levels for uses such as characterizing a risk profile for developing diabetes in an apparently healthy individual or evaluating the likelihood that an individual will benefit from treatment given CRP's known association with type II diabetes, as taught by Rodriguez-Moran et al., given that it is well known to measure a known marker for the presence of, or predisposition to, diabetes, as taught by Rohlfing et al., even in apparently healthy individuals because even apparently health individuals can suffer from undiagnosed diabetes and/or complications thereof, as taught by Chapin et al. Note that the choice of any particular serum CRP concentration as an indicator of disease comprises no more than routine optimization of the claimed method and falls well within the purview of the ordinarily skilled artisan.

Applicant's arguments filed 8/08/07 have been addressed by the additional references in the rejection. In particular, Chapin et al. demonstrates that even apparently healthy individuals who undergo regular physical examinations can suffer from undiagnosed diabetes and/or complications thereof.

Further, Applicant's argument that, "When individuals with noncontrolled diabetes are examined by a medical professional they will not be characterized as healthy and free of symptoms of disease. Instead, such individuals will be characterized as diabetic and will likely be treated", has not been found to be persuasive. Blood assays for diseases not readily apparent to an examining physician are well-known, e.g., a PSA assay for prostate cancer.

Applicant makes a curious argument that the teachings of Rodriguez-Moran et al. cannot be used to render obvious the predictive value of CRP levels for future diabetes. Applicant is advised that if this argument were to be found persuasive

then a rejection for lack of enablement would be required given the fact that the example in the specification does not show said predictive value either. It is noted that the subjects of the study were merely *asked* if they were free of diabetes; there is no showing that they were not suffering from uncontrolled diabetes at the time of their enrollment in the study (page 24).

7. Claims 1, 6, 11, 16, 21, 52, 55, 57, 62-68, and 71-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schalkwijk et al. (1999) in view of Rohlfing, C.L., et al. (2000) and Chapin. B.L., et al. (1999).

Schalkwijk et al. teaches that elevated serum CRP levels have been found in type I diabetics and in diabetics with foot ulcers (see particularly page 211, **Results** and Table 2).

Schalkwijk et al. does not teach the characterizing a risk profile for developing diabetes in an apparently healthy individual nor evaluating the likelihood that an individual will benefit from treatment.

Rohlfing et al. and Chapin et al. have been discussed above.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made measure serum CRP levels for uses such as characterizing a risk profile for developing diabetes in an apparently healthy individual or evaluating the likelihood that an individual will benefit from treatment given CRP's known association with type I diabetes, as taught by Schalkwijk et al., given that it is well known to measure a known marker for the presence of, or predisposition to, diabetes, as taught by Rohlfing et al., even in apparently healthy individuals because even apparently health individuals can suffer from undiagnosed diabetes and/or complications thereof, as taught by Chapin et al. Note that the choice of any particular serum CRP concentration as an indicator of disease comprises no more than routine optimization of the claimed method and falls well within the purview of the ordinarily skilled artisan.

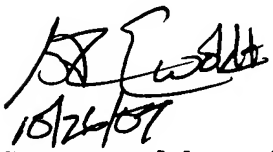
Applicant presents arguments essentially the same as presented regarding the rejection in view of Rodriguez-Moran et al.

See the Examiner's response in Section 6.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571)272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.


10/24/07

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600